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EXAMINER	
FISHER, ABIGAIL L	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/017,568	ZEMEL ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-27,29,35-38,41,42,46-68,78 and 79* is/are pending in the application.

4a) Of the above claim(s) *22,25-27,29,42,46-49,51-54,59,60 and 64-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,23,24,35-38,41,50,55-58,61-63,78 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks filed on November 10 2008 is acknowledged. Claims 1-20, 28, 30-34, 39-40, 43-45 and 69-77 were/stand cancelled. Claims 24, 38 and 41 were amended. Claims 78-79 were added. Claims 21-27, 29, 35-38, 41-42, 46-68 and 78-79 are pending. Claims 22, 25-27, 29, 42, 46-49, 51-54, 59-60 and 64-68 are withdrawn as being directed to a non-elected invention. Claims 21, 23-24, 35-38, 41, 50, 55-58, 61-63 and 78-79 are directed to the elected invention.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on November 10 2008 was considered by the examiner.

Claim Warning

Applicant is advised that should claim 24 be found allowable, claim 41 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 21, 23, 35-40, 50, 55-58 and 63 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **withdrawn** in light of Applicants amendments filed on November 10 2008 specifically indicating the antagonists of calcitrophic hormone activity.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 23-24, 35-38, 41, 50, 55-58, 61-63 and 78-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21 and 23 depend from claim 38 wherein claim 38 recites specific receptor antagonists of calcitrophic hormone activity. However claim 21 claims the administration of a 1,25-dihydroxyvitamind D receptor antagonist and 23 claims that the antagonist is a chemical compound that binds to said 1,2-$(OH)_2$-D receptor. Therefore, claims 21 and 23 are attempting to claim a broader group of receptor antagonists. This results in indefinite claims because firstly it is unclear how the claims further limit claim 38 and secondly the resulting claims do not clearly set forth the metes and bounds of the patent protection desired as to the antagonist attempting to be claimed in instant claims 21 and 23.

Claim 38 recites that, "said antagonist inducing weight loss, attenuating, controlling and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue". While inducing weight loss and increasing metabolic consumption of adipose tissue are definite, attenuating, controlling and/or reducing weight gain are indefinite. Applicants have provided no definitions for attenuating, controlling or reducing weight gain. Therefore, the examiner must take the most reasonable definition. The Merriam Webster dictionary indicates that attenuating by definition means to make thin or slender or to lessen. Therefore attenuating weight gain must mean to lessen weight gain. Controlling weight gain can also be reasonably interpreted as lessening weight gain. Reducing weight gain as well would reasonably be interpreted as lessening weight gain. Therefore attenuating, controlling and reducing weight gain would all reasonably be interpreted as meaning the same thing. Subsequently it is unclear what the scope or metes and bounds of the desired patent protection desired for each of the different reductions of weight gain.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 21, 23, 38-39, and 57 are rejected under 35 U.S.C. 102(a) as being anticipated by McCarthy (Remedy, March/April 2000) is **withdrawn** in light of

Applicants arguments and Rule 132 Declaration filed on November 10 2008 indicating that the results presenting in McCarthy are solely by the instant inventor.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 21, 23, 28, 38-40, 50 and 56-58 under 35 U.S.C. 103(a) as being unpatentable over Larsson et al. (Clinical Orthopaedics and Related Research, 1977) is **withdrawn** in light of Applicants arguments filed on November 10 2008 that 1,25-DHCC is 1α,25-$(OH)_2$ D_3, which is an agonist of Vitamin D. Although 1α,25-$(OH)_2$ D_3 is an isomer of 1β,25-$(OH)_2$ D_3, it is excluded as a specie of independent claim 38 which recites the isomer of 1β,25-$(OH)_2$ D_3 is an antagonist.

The rejection of claims 35-37 under 35 U.S.C. 103(a) as being unpatentable over Larsson et al. in view of Jequier (Am. J. Clin. Nutr. 1987) is **withdrawn** in light of Applicants arguments filed on November 10 2008.

The rejection of claims 24, 40-41, 50, 55-56, 58 and 63 under 35 U.S.C. 103(a) as being unpatentable over McCarthy (Remedy, March/April 2000) in view of Norman et al. (JBC, 1993, cited on PTO Form 1449) is **withdrawn** in light of Applicants arguments and Rule 132 declaration filed on November 10 2008.

The rejection of claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarthy in view of Jequier is **withdrawn** in light of Applicants arguments and Rule 132 declaration filed on November 10 2008.

Claims 21, 23-24, 38, 41, 50, 55-58 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norman et al. (US Patent No. 6103709) in view of Xue et al. (FASEB J, 1998).

Applicant Claims

Applicant claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-$(OH)_2$-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue. A specific antagonist is 1β, 25-dihydroxyvitamin D_3.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Norman et al. is directed to therapeutically effective 1α, 25-dihydroxyvitamin D_3 analogues and methods for the treatment of Vitamin D diseases. It is taught that the invention covers a method for the treatment of diseases caused by a deficiency or overproduction of vitamin D_3 metabolites. These diseases include osteoporosis, parathyroid diseases which includes secondary parathyroidism and for the treatment of any other disease in which 1α, 25-dihydroxyvitamin D_3 or its prodrugs are involved (column 1, lines 24-47). Analogs of 1α, 25-dihydroxyvitamin D_3 include 1β, 25-dihydroxyvitamin D_3 which is specifically taught as an antagonist of 1α, 25-dihydroxyvitamin D_3 (column 5, lines 24-28, Figure 13 and Table I and 6). It is taught that occupancy of the VDR_{mem} leads to activation of a variety of intracellular messengers. It is taught that in cells that have a VDR_{mem} linked to a calcium channel

there is an increase in Ca^{2+} (calcium) ions moving into the cells which results in an increase in intracellular calcium concentrations. Opening of the calcium channel followed by the intracellular calcium increase results in increased activities of the osteoblasts, and secretion of insulin (column 12, lines 39-59 and Figure 6). Therefore, as one can see from figure 6, the natural hormone, 1α, 25-$(OH)_2D_3$, causes an increase in intracellular calcium. It is taught that 1β, 25-dihydroxyvitamin D_3 is an antagonist of the VDR_{mem}(column 14, lines 54-55). Therefore, Norman et al. teaches that 1β, 25-dihydroxyvitamin D_3 inhibits intracellular calcium increase. It is taught that pharmaceutical compositions useful for the treatment of vitamin D disorders comprise an effective amount of the analog (agonist or antagonist) in acceptable non-toxic carriers (column 33, lines 60-65). Compositions for oral or parenteral can be prepared by dissolving, dispersing, suspending, etc. The analog in a suitable carrier such as water, saline, or other liquids (column 34, lines 45-57).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Norman et al. do not teach that the disease in which 1α, 25-dihydroxyvitamin D_3 or its prodrugs are involved is obesity or other weight related diseases. However, this deficiency is cured by Xue et al.

Xue et al. teach that intracellular calcium plays an important role in the metabolic disorder of obesity and insulin resistance (page 1392, left column first paragraph). It is taught that recent data has demonstrated that increasing intracellular calcium inhibits lipolysis in a dose dependent manner (page 1392, left column, second paragraph). Since lipolysis is the process whereby fat stored in cells is broken down, if lipolysis is

inhibited then fat is not broken down. Furthermore, it is postulated by Xue et al. that intracellular calcium plays an important role in the metabolic disorder of obesity and insulin resistance. Obese patients' exhibit elevated basal intracellular calcium levels in adipocytes and that elevating intracellular calcium results in reduced lipolysis (page 1395, third paragraph).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Norman et al. and Xue et al. and utilize 1β, 25-dihydroxyvitamin D_3 in a method of regulating weight by reducing weight gain. One of ordinary skill in the art would have been motivated to utilize 1β, 25-dihydroxyvitamin D_3 in a method of reducing weight as Xue et al. teach that an increase in intracellular calcium inhibits lipolysis which prevents stored fat from being broken. Since one of ordinary skill in the art would know from the teachings of Norman et al. that 1α, 25-dihydroxyvitamin D_3 causes an increase in intracellular calcium, it would have been obvious to one of ordinary skill in the art to administer an antagonist of 1α, 25-dihydroxyvitamin D_3 such as 1β, 25-dihydroxyvitamin D_3 in order to stop the inhibition of lipolysis caused by 1α, 25-dihydroxyvitamin D_3. Furthermore, it would have been obvious to one of ordinary skill in the art to administer 1β, 25-dihydroxyvitamin D_3 in order to control intracellular calcium as Xue et al. teach that intracellular calcium plays an important role in the metabolic disorder of obesity and insulin resistance.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Norman et al. and Xue et al. and formulate 1β, 25-dihydroxyvitamin D_3 into a liquid pharmaceutical composition. One of ordinary skill in the art would have been motivated to formulate a liquid pharmaceutical composition as Norman et al. teach that this is a suitable form to administer 1β, 25-dihydroxyvitamin D_3 either orally or parenterally. It would have been obvious to one of ordinary skill in the art to formulate the 1β, 25-dihydroxyvitamin D_3 into suitable pharmaceutical composition form depending on the desired form of delivery.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norman et al. in view of Xue et al. and in further view of Jequier (Am. J. Clin. Nutr. 1987, cited in the Office action mailed on July 10 2008).

Applicant Claims

Applicant claims that the individual has Grade I, Grade II and Grade III obesity (separately claimed).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Norman et al. and Xue et al. are set forth above. Specifically, Norman et al. teach that 1β, 25-dihydroxyvitamin D_3 is an antagonist of 1α, 25-

dihydroxyvitamin D_3 and can be utilized to treat vitamin D related disorders. Norman et al. additionally teach that 1α, 25-dihydroxyvitamin D_3 causes an increase in intracellular calcium. Xue et al. teach that obese patients exhibit elevated basal intracellular calcium levels in adipocytes and that elevating intracellular calcium results in reduced lipolysis.

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Norman et al. do not specify administration to individuals with Grade I, Grade II, or Grade III obesity. However, this deficiency is cured by Jequier.

Jequier discloses that desirable range of a BMI for women and men is between 20-25. Grade 1 obesity corresponds to a BMI of 25-29.99. Grade II of 30-40 and Grade III greater than 40. The health risks associated with obesity include mortality, dyslipidemia, hypertension, or diabetes (page 1035, left column, 2nd and 3rd paragraphs).

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Norman et al., Xue et al. and Jequier and administer 1β, 25-dihydroxyvitamin D_3 to individuals with Grade I, Grade II, and Grade III obesity. One of ordinary skill in the art would have been motivated to administer 1β, 25-dihydroxyvitamin D_3 to these types of individuals because they are great risk for developing diseases and even death as taught by Jequier. One of ordinary skill in the art would have been motivated to administer 1β, 25-dihydroxyvitamin D_3 to obese individuals as Xue et al. teach that obese patients exhibit elevated basal intracellular

calcium levels in adipocytes and that elevating intracellular calcium results in reduced lipolysis and Norman et al. teach that 1β, 25-dihydroxyvitamin D_3 is an antagonist of 1α, 25-dihydroxyvitamin D_3 increase in intracellular calcium.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 21, 23, 35-38, 50, 55-58, 61-63 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Study: Calcium May Curb Weight Gain in Young Women (http://www.sciencedaily.com/releases/1999104199042107360 8.htm, April 21 1999, referred to in the Office action as "Science Daily", cited in PTO Form 1449) in view of Summerbell et al. (BMJ, cited on PTO Form 1449) and Jequier.

Applicant Claims

Applicant claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-$(OH)_2$-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue. A specific antagonist is calcium.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Science Daily is directed to a study of the effect of calcium on weight gain. It is disclosed that when overall calorie consumption is account for, calcium not only helps to keep weight in check but can be associated specifically with decreases in body fat (paragraph 1). It is disclosed that when women of the study consumed a diet of 1900 calories or less, those who consumed an average of 1000 mg of calcium per day showed an overall decrease in body weight (paragraph 4 and 5) especially when compared to women those consumed less than 1900 calories but averaged less than 780 mg of calcium per day. The women who averaged less than 780 mg of calcium actually gained body fat mass over the same period (paragraph 4). Women who received their calcium from dairy sources such as milk, yogurt and cheese showed more benefits than those who primarily used non-dairy sources such as vegetables, nuts, beans, and calcium supplements (paragraph 8). It is disclosed that women who consume calcium from dairy products or who consume at least 1000 mg per day of calcium may reap the most benefit (abstract, second paragraph).

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Science Daily does not specify utilizing calcium to induce weight loss in obese women. However, this deficiency is cured by Summerbell et al. and Jequier.

Summerbell et al. is directed to weight reducing diets. The diets of the trial were directed to reducing weight in patents with a body mass index (BMI) greater than 27 (abstract). Three diets were administered. Diet 1 was a control. Diet 2 was a milk only diet. Diet three was a milk plus diet, which consisted of milk with the addition of

unlimited amount of a single food (page 1488, interventions). It is disclosed that in the milk only diet patients achieved the highest overall mean weight loss (page 1489, first paragraph).

Jequier discloses that desirable range of a BMI for women and men is between 20-25. Grade 1 obesity corresponds to a BMI of 25-29.99. Grade II of 30-40 and Grade III greater than 40. The health risks associated with obesity include mortality, dyslipidemia, hypertension, or diabetes (page 1035, left column, 2nd and 3rd paragraphs).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Science Daily, Summerbell et al. and Jequier and administer calcium to individuals with Grade I, Grade II, and Grade III obesity in regulate weight. One of ordinary skill in the art would have been motivated to administer calcium to these types of individuals because they are great risk for developing diseases and even death as taught by Jequier. One of ordinary skill in the art would have been motivated to administer calcium to obese individuals as Science Daily teach that administration of calcium causes an overall decrease in body weight. Additionally, Summerbell et al. indicates that this type of administration has been shown to induce weight loss in obese patients.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the

instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Science Daily in view of Summerbell et al. and Jequier and in further view of Peterson et al. (Journal of Nutrition, 1992).

Applicant Claims

Applicant claims that the form of calcium is calcium carbonate.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Science Daily, Summerbell et al., Jequier and Peterson et al. are set forth above. Specifically, Science Daily teaches that administration of calcium causes a decrease in body weight. Sources of calcium include milk, yogurt, cheese, leafy vegetables, beans, calcium supplements etc.

Ascertainment of the Difference Between Scope the Prior Art and the Claims *(MPEP §2141.012)*

Science Daily does not specify that the source of the calcium is calcium carbonate. However, this deficiency is cured by Peterson et al.

Peterson et al. teach that calcium is found in spinach, nonfat dry milk, calcium carbonate, cheese, tofu, or tortillas (page 137, right column, last paragraph).

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Science Daily, Summerbell et al., Jequier

and Peterson et al. and utilize calcium in the form of calcium carbonate. One of ordinary skill in the art would have been motivated to utilize calcium carbonate as Science Daily teaches that administration of calcium causes a decrease in body weight and Peterson et al. teach sources of calcium include milk, cheese, spinach as well as calcium carbonate. It would have been obvious to one of ordinary skill in the art to obtain calcium from commonly known sources such as calcium carbonate. Furthermore, Science Daily teaches that sources of calcium include milk and cheese. Therefore, one of ordinary skill in the art would have been motivated to replace milk and cheese with calcium carbonate as all are taught by Peterson et al. as functional equivalents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21, 23, 35-38, 50, 55-58, 61-63 and 78-79 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6384087 in view of Jequier. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims a method of regulating body weight comprising administering an antagonist of calcitrophic hormone (1,25-$(OH)_2$-D) activity in an amount effective to block calcitrophic hormone activity in adipocytes of said individual, said antagonist inducing weight loss, attenuating, controlling, and/or reducing weight gain and/or increasing metabolic consumption of adipose tissue. A specific antagonist is calcium. The individual has Grade I, II, or III obesity.

Patent '087 claims a method of treating, reducing, or attenuating obesity in an individual comprising the administration of therapeutically effective amounts of calcium to an individual and inducing a metabolic change in said individual. The claimed metabolic change is decreasing intracellular calcium concentrations, stimulating lipolysis, inhibiting lipogenesis, etc. The calcium administered is contained in dairy

products, a dietary supplement, foodstuffs supplemented with calcium and other foods high in calcium.

Patent '087 does not claim administration of the calcium to individuals who are obese. However, this deficiency is cured by Jequier.

Jequier discloses that desirable range of a BMI for women and men is between 20-25. Grade 1 obesity corresponds to a BMI of 25-29.99. Grade II of 30-40 and Grade III greater than 40. The health risks associated with obesity include mortality, dyslipidemia, hypertension, or diabetes (page 1035, left column, 2nd and 3rd paragraphs).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Patent '087 and Jequier and administer calcium to individuals with Grade I, Grade II, and Grade III obesity. One of ordinary skill in the art would have been motivated to administer calcium to these types of individuals because they are great risk for developing diseases and even death as taught by Jequier. One of ordinary skill in the art would have been motivated to administer calcium as Patent '087 is directed to a method of treating and reducing obesity. Therefore, it would have been obvious to one ordinary skill in the art to administer calcium to obese individuals to reduce their obesity.

Therefore, the scopes of the patent claims and the instant application overlap and thus they are obvious variants of one another.

Claims 21, 23, 35-38, 50, 55-58, 61-63 and 78-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being

unpatentable over claims 1-7, 10-15 of copending Application No. 10/827296. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant application claims are set forth above

Copending '296 claims a method of avoid health problems in an individual at risk thereof due to excess body weight and/or an excess of body fat, the individual suffering form at least Grade I obesity, comprising in combination during a period of time: administer to the individual one or more servings of a dairy product comprising a sufficient amount of dietary calcium of at least about 773 mg per day to induce weight loss, reduce weight gain, and/or increase the metabolic consumption of adipose tissue in the individual, and maintaining the individual on a restricted caloric diet below ad lib in a range of about 200 kcal to about 2500 kcal per day, wherein the individual is a women and the one or more servings is at least about 57 servings of dairy per month.

Copending '296 does not claim specific sources of the calcium. The difference between the instant application and copending '296 is that the instant application claims specific types of calcium sources.

The relationship between the instant application and copending '296 is a genus-species relationship. Calcium carbonate and dietary calcium are particular types of calcium sources. Therefore, both the instant application and copending '296 are directed to similar subject matter.

Thus, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21, 23, 35-38, 50, 55-58, 61-63 and 78-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 10-17, 19-22 of copending Application No. 10/827307. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '307 claims a method of including weight loss and/or increasing the metabolic consumption of tissue in an individual suffering from obesity, wherein obesity is selected from the group consisting of Grade I, Grade II, and Grade III obesity, wherein the method comprising in combination during a period of time administering to the obese individual one or more servings of one more calcium calcium-containing products where the one or more servings comprise an amount of dietary calcium of at least about 773 mg per day, sufficient to include with loss, and/or increase the metabolic consumption of adipose tissues, and restricting said obese individual to a caloric intake below ad lib in a range of about 200 kcal to about 2500 kcal per day where in the individual is a women and the one or more servings comprise at least about 57 servings of dairy per month.

Copending '307 does not claim specific sources of the calcium. The difference between the instant application and copending '307 is that the instant application claims specific types of calcium sources.

The relationship between the instant application and copending '307 is a genus-species relationship. Spinach, supplements, diary products, etc. are particular types of calcium sources. Therefore, both the instant application and copending '307 are directed to similar subject matter.

Thus, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21, 23, 35-38, 50, 55-58, 61-63 and 78-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-6, 28-37, 41-44, 46-53, 55, 57, 59-62, 64-72 of copending Application No. 10066057. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope.

The instant claims are set forth above.

Copending '057 claims a method of inducing weight loss comprising administer one or more servings of one or more calcium containing products and reducing the

caloric intake of obese individuals. The calcium sources as claimed include calcium-containing dietary supplement.

Therefore both the instant application and copending '057 are directed to methods of inducing weight loss in obese individuals who are obese. Thus, the scopes of the copending claims overlap and thus they are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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